

FDA-Approved Rapid HIV Antibody Screening Tests

January 10, 2005

	<u>FDA Approval Received</u>	<u>Specimen Type</u>	<u>CLIA Category*</u>	<u>Sensitivity** (95% CI)</u>	<u>Specificity** (95% CI)</u>	<u>Manufacturer</u>	<u>Approved for HIV-2 Detection?</u>	<u>List Price Per Device^</u>	<u>External Controls</u>
OraQuick Rapid HIV-1 Antibody Test	Nov 2002	Whole blood (fingerstick or venipuncture)	Waived	99.6% (98.5-99.9)	100% (99.7-100)	OraSure Technologies, Inc. www.orasure.com	No	\$14.50	Sold Separately (\$20 each)
OraQuick ADVANCE Rapid HIV-1/2 Antibody Test	Mar 2004	Oral fluid	Waived	99.3% (98.4-99.7)	99.8% (99.6-99.9)	OraSure Technologies, Inc. www.orasure.com	Yes	\$17.50	Sold Separately (\$25 each)
		Whole Blood (finger stick or venipuncture)	Waived	99.6% (98.5-99.9)	100% (99.7-100)				
		Plasma	Moderate Complexity	99.6% (98.9-99.8)	99.9% (99.6-99.9)				
Uni-Gold Recombigen HIV	Dec 2003	Whole blood (fingerstick or venipuncture)	Waived	100% (99.5-100)	99.7% (99.0-100)	Trinity Biotech www.unigoldhiv.com	No	\$15.75	Sold Separately (\$26.25 each)
		Serum & Plasma	Moderate Complexity	100% (99.5-100)	99.8% (99.3-100)				
Reveal G-2 Rapid HIV-1 Antibody Test	Apr 2003	Serum	Moderate Complexity	99.8% (99.5-100)	99.1% (98.8-99.4)	MedMira, Inc. www.medmira.com	No	\$14.00	Included
		Plasma	Moderate Complexity	99.8% (99.5-100)	98.6% (98.4-98.8)				
MultiSpot HIV-1/HIV-2 Rapid Test	Nov 2004	Serum	Moderate Complexity	100% (99.94-100)	99.93% (99.79-100)	BioRad Laboratories www.biorad.com	Yes – differentiates HIV-1 from HIV-2	\$25.00	Included
		Plasma	Moderate Complexity	100% (99.94-100)	99.91% (99.77-100)				

Clinical Laboratory Improvement Amendments: CLIA regulations identify three categories of tests: waived, moderate complexity, or high complexity

** Sensitivity is the probability that the test result will be reactive if the specimen is a true positive; specificity if the probability that the test result will be nonreactive if the specimen is a true negative. Data are from the FDA summary basis of approval, for HIV-1 only. For HIV-2 information, see package inserts.

^ Actual price may vary by purchasing agreements with manufacturers

Note. Trade names are for identification purposes only and do not imply endorsement.

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